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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,126	10/20/2004	Jin-Hee Choi	9717.40USWO	8435
23552	7590	11/07/2006		
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903				
EXAMINER ANDERSON, JAMES D				
ART UNIT		PAPER NUMBER		
1614				

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/512,126

Applicant(s)

CHOI ET AL.

Examiner

James D. Anderson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10 and 11 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1 sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 1-8 and 10-11 are currently pending and are the subject of this Office Action. Applicants in the preliminary amendment filed 10/20/2004 canceled claims 9 and 12-13. This is the first Office Action on the merits of the application.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/20/2004 is being considered by the examiner to the extent that each reference cited therein is a proper citation. Please see attached Form 1449.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-8 and 10-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,578,641 (Issued 11/26/1996).

Examiner has interpreted the instant claims as being drawn to compositions comprising N,N-dimethylphytosphingosine as an active ingredient. Applicants are reminded that intended use is not given patentable weight in claims drawn to compositions.

The '641 patent teaches pharmaceutical compositions comprising one or more ceramide pathway intermediates or precursors (Abstract). Said intermediates or precursors comprise sphinganine, sphingosine, phytosphingosine and derivatives thereof, including the instantly claimed N,N-dimethylphytosphingosine (col. 3, line 40 to col. 5, line 58; see especially col. 5, lines 34-42). The compounds of the invention are incorporated into compositions comprising solid, semi-solid or liquid cosmetically and/or physiologically acceptable vehicles (col. 5, lines 60-64; col. 6, lines 7-22). Further, '641 teaches kits comprising the compositions, including packaging in a bottle or propellant-driven aerosol device (col. 13, lines 33-50).

The preambles of the instant claims recite intended uses, *e.g.* "An anti-cancer composition..." (Claim 1); "A sphingosine kinase inhibitor composition..." (Claim 6); "An apoptosis inducing composition..." (Claim 7); "A protein kinase inhibitor composition..." (Claim 8); "A composition for treating..." (Claim 10) and are viewed as non-limiting since they do not recite essential steps "necessary to give life, meaning and vitality" to the claimed subject matter.

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Pitney Bowes, 61 USPQ2d at 1165-66; *Kropa v. Robie*, 88 USPQ 478, 480-81 (CCPA 1951).

The body of the claims following the preamble are self-contained descriptions of the invention (“...composition comprising N,N-dimethylphytosphingosine as an active ingredient”) and do not depend on the preamble for completeness. Accordingly, even when prior art compositions are used to treat other indications or inhibit other pathways, they anticipate the instantly claimed compositions because they recite a composition comprising the instantly claimed compound.

As such, the ‘641 patent anticipates the instant claims because it teaches pharmaceutical compositions comprising the instantly claimed compound.

Allowable Subject Matter

Claims 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not teach a composition comprising N,N-dimethylphytosphingosine and further comprising phytosphingosine, acetylated phytosphingosine or ethylated phytosphingosine in a weight ratio of 1:1.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038.

The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

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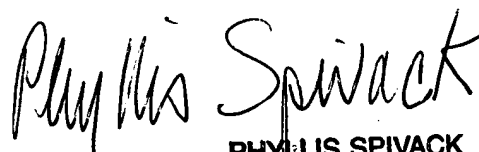
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson, Ph.D.
Patent Examiner
AU 1614

November 3, 2006



PHYLLIS SPIVACK
PRIMARY EXAMINER 11/3/06